

K132654  
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**510(k) Summary**  
**Prepared July 26, 2013**

**Sponsor:** Siemens Medical Solutions, Inc.,  
Ultrasound Division  
685 East Middlefield Road  
Mountain View, California 94043

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**Submission Date:** July 26, 2013

**Device Name:** Acuson SC2000™ Diagnostic Ultrasound System

**Common Name:** Diagnostic Ultrasound System

**Classification:**

Regulatory Class: II  
Review Category: Tier II  
Classification Panel: Radiology

Ultrasonic Pulsed Doppler Imaging System	FR # 892.1550	Product Code 90-IYN
Ultrasonic Pulsed Echo Imaging System	FR # 892.1560	Product Code 90-IYO
Diagnostic Ultrasound Transducer	FR # 892.1570	Product Code 90-ITX
Diagnostic Intravascular Catheter	FR # 870.1200	Product Code OBJ

**A. Legally Marketed Predicate Devices**

The Acuson SC2000™ Ultrasound System in this 510k is a modification to SC2000™ Diagnostic Ultrasound System previously cleared in K072365, K102017, K113179, K123622 and K130754.

**B. Device Description:**

The SC2000™ Diagnostic Ultrasound System is a multi-purpose mobile, software controlled diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bio-effect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data and display it in B-Mode, M-Mode, Pulsed (PW) Doppler Mode, Continuous (CW) Doppler Mode, Color Doppler Mode, Amplitude Doppler Mode, a combination of modes, 3D Imaging, or Harmonic Imaging and 4D imaging on a Flat Panel Display.

The SC2000™ Ultrasound System has been optimized for user ergonomics with adjustable keyboard height and rotation and independently adjustable Flat Panel Display. There is an available off-line workstation (SC2000WP)

### C. Intended Use

The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal and Fetal Cardiac, Pediatric, Transesophageal, Adult Cephalic, Peripheral Vessel, Abdominal, Intraoperative Abdominal, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications. The system also provides the ability to measure anatomical structures and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes. The typical examinations performed using the SC2000 Ultrasound System are:

#### **Cardiac Imaging Applications and Analysis**

The system transmits ultrasound energy into adult, pediatric, neonatal, and fetal cardiac patients creating 2D (B), 3D, M-Mode (M), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave (PW) Doppler, and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the heart, cardiac valves, great vessels, and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system also supports catheters which are intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients.

The system has Cardiac Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

#### **Vascular Imaging Applications and Analysis**

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the carotid arteries or jugular veins in the neck; superficial and deep veins and arteries in the arms and legs; and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system has Vascular Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

#### **Superficial Imaging Applications**

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of conventional or superficial musculoskeletal structures and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

#### **Intraoperative Imaging Applications**

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), and Pulsed Wave Doppler (PWD) to obtain images and blood flow velocity that provide guidance during intraoperative procedures.

#### **Transcranial Imaging Applications**

The system transmits ultrasound energy into the cranium of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the brain and surrounding anatomical structures to evaluate the presence or absence of pathology.

The system provides Measurement Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

#### D. Substantial Equivalence

The submission device is a modification to SC2000™ Diagnostic Ultrasound System previously cleared in K072365, K072786, K102017, K113179, K123622 and K130754 with regard to both intended use and technological characteristics.

Description	Acuson SC2000™ K123622	Acuson S2000 K111674	Acuson S2000 K072786	Acuson SC2000™ This submission
<b>System</b>				
Hardware Safety – EN60601-1 Certified	X	X	X	X
Software Safety – EN60601-4 Certified	X	X	X	X
Acoustic Thermal Safety – EN60601-2-37 Certified	X	X	X	X
<b>Transducers</b>				
See Table In Section 4.4.1.4 – All previously cleared	X	X	X	X
Biocompatibility – Same transducers no new materials	X	X	X	X
6C1HD Transducer		X		X
AcuNav 8F/10F	X	X		X
AcuNav V	X	X		X
Soundstar 10F	X	X		X
Biocompatibility – Same transducers no new materials	X	X	X	X
<b>Accessories</b>				
Respirometer	X			X
AcuNav Joystick	X	X		X
<b>Imaging</b>				
SpaceTime™ resolution control	X	X	X	X
Native™ Tissue Harmonic Imaging	X	X	X	X
MultiHertz multiple frequency imaging	X	X	X	X
RES™ enhanced resolution imaging format	X	X	X	X
Output display standard compliance	X	X	X	X
Native TEQ™ dynamic ultrasound technology	X	X	X	X
TEQ™ ultrasound technology	X	X	X	X
TEQ™ technology for Spectral PW and CW Doppler	X	X	X	X
Dual screen and live dual imaging	X	X	X	X
Acoustic clip capture	X	X	X	X
eSie Measure Workflow Acceleration	X	X	X	X
Preset functionality with preset ordering and grouping capabilities and linking to MultiHertz™ multiple frequency imaging	X	X	X	X
Integrated Stress echo capability	X			X
Cardiac imaging and quantification package	X			X

DTI™ Doppler tissue imaging includes the following color Doppler capabilities:	X	X	X	X
DTI Velocity (DTV)	X	X	X	X
Color Doppler Harmonic capability in DTI	X	X	X	X
High Frame Rate Tissue Doppler (HTD) Capability	X	X	X	X
DTI Energy (DTE)	X	X	X	X
Color Doppler Velocity (CDV)	X	X	X	X
Color Harmonic imaging	X	X	X	X
DTI Pulsed Wave (DTI PW) capability	X	X	X	X
Color Doppler M-Mode for:	X	X	X	X
CDV	X	X	X	X
DTV	X	X	X	X
DTE	X	X	X	X
<b>Contrast Imaging</b>				
Cadence™ contrast pulse sequencing technology (CPS)	X	X	X	X
PrecisionBurst programmable triggering for contrast agent destruction	X	X	X	X
TEQ and NTEQ ultrasound technology for Cadence™ CPS	X	X	X	X
<b>Cardiac Calculations</b>				
Cardiac calculations package	X			X
Slope Line calculations	X			X
Generic Calculations/Ratio function	X			X
<b>Vascular Imaging Package</b>				
B-mode, M-mode, NTHI, CPS, PW Doppler, Triplex imaging and High Resolution Color Flow (HRCF)	X	X	X	X
Cadence™ CPS Capture	X	X	X	X
Advanced SieClear™ spatial compounding with Dynamic TCE™ (tissue contrast enhancement) technology	X	X	X	X
Advanced Vascular Analysis report package	X	X	X	X
Clarify™ Vascular Enhancement Technology		X	X	X
Linear and Vector imaging formats	X	X	X	X
Auto Doppler option	X	X	X	X
Time averaged velocity (TAV) calculation	X	X	X	X
Vascular Calculation package	X	X	X	X
Transcranial Imaging	X	X	X	X
<b>Application Packages</b>				
syngo® Mitral Valve Assessment	X	X	X	X
syngo® auto Ejection Fraction technology	X	X	X	X
DfART with syngo® fourSight™ TEE view	X	X	X	X
syngo® Quantitative Synch Tools™ technology (QST)	X	X	X	X
syngo® Velocity Vector Imaging™ technology (VVI) rotation	X	X	X	X
syngo® ACQ auto-tracking contrast quantification	X	X	X	X

Connectivity				
Wireless Network Connectivity	X			X
DICOM Print Service	X	X	X	X
DICOM Media Storage Service	X	X	X	X
DICOM Structured Reporting	X	X	X	X

### Technological Comparison

The new feature, Clarify VE, or Clarify is the same feature used on the S2000 (K072786). Clarify vascular enhancement technology uses power Doppler flow information to enhance B-mode tissue resolution and reduce acoustic clutter throughout the region of interest. Clarify also provides clearer vessel wall definition, improves tissue boundary detection and tissue contrast resolution, while preserving spatial resolution.

### Similarities

As can be seen from the comparison table and the device description above, the modified device has substantially equivalent indications for use and technological characteristics as the predicate devices ACUSON S2000 (K111674, 072786) and ACUSON SC2000 (K113179)

### Differences

There are no differences for the new transducer (6C1HD) and feature (Clarify VE) from its use in S2000.

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#### E. Performance Data

The SC2000™ is designed, verified, and validated according to the company's design control process and has been subjected to extensive safety and performance testing before release. Final testing of the SC2000 included various safety and performance testing designed to ensure the device meets all of its specifications. Safety tests have been performed to ensure the device complies with applicable industry and safety standards including:

The Acuson SC2000™ has been designed to meet the following product safety standards:

- UL 60601-1, Safety Requirements for Medical Equipment
- IEC 60601-2-37 Diagnostic Ultrasound Safety Standards
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-2, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- Safety and EMC Requirements for Medical Equipment
  - IEC 60601-1
  - IEC 60601-1-1
  - IEC 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993-1 Biocompatibility

#### F. Summary

Intended uses and other key features are consistent with traditional clinical practice and FDA guidelines. The design and development process of the manufacturer conforms with 21 CFR 820 Quality System Regulation and ISO 13485:2003 quality system standards. The product is designed to conform to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore it is the opinion of Siemens Medical that the SC2000 systems are substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

Siemens Medical Solutions USA, Inc.  
% Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services LLC  
1394 25th Street NW  
BUFFALO MN 55313

September 26, 2013

Re: K132654  
Trade/Device Name: Acuson SC2000™ Diagnostic Ultrasound System  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, ITX and OBJ  
Dated: August 21, 2013  
Received: September 4, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Acuson SC2000™ Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Numbers

9L4	6C1HD	V5M
4V1c	8V3	CW2
4Z1c	V7M	10V4

AcuNav 8F and 10F Ultrasound Catheter  
ACUSON AcuNav™ V 10F Ultrasound Catheter  
SoundStar 10F Ultrasound Catheter

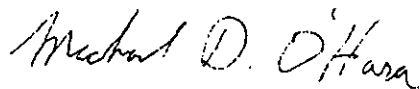
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
for

Janine M. Morris  
Director, Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure



## **Diagnostic Ultrasound Indications for Use Form**

**510(k) Number (if known):** K132654

**Device Name:** SC2000™ Diagnostic Ultrasound System

### **Indications for Use:**

The SC2000 ultrasound imaging system is intended for the following applications: Cardiac, Neo-natal and Fetal Cardiac, Pediatric, Transesophageal, Adult Cephalic, Peripheral Vessel, Abdominal, Abdominal Intraoperative, Intraoperative, Musculo-skeletal Conventional, and Musculo-skeletal Superficial applications. The system also provides the ability to measure anatomical structures and calculation packages that provide information to the clinician that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes. The typical examinations performed using the SC2000 Ultrasound System are:

#### **Cardiac Imaging Applications and Analysis**

The system transmits ultrasound energy into adult, pediatric, neonatal, and fetal cardiac patients creating 2D (B), 3D, M-Mode (M), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave (PW) Doppler, and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the heart, cardiac valves, great vessels, and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system also supports catheters which are intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients.

The system transmits ultrasound energy from either a transthoracic or transesophageal approach in adult and pediatric patients; and from a transthoracic approach in neonatal and fetal cardiac patients creating 2D (B), 3D, M-Mode (M), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave (PW) Doppler, and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the heart, cardiac valves, great vessels, and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system has Cardiac Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

#### **Vascular Imaging Applications and Analysis**

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the carotid arteries or jugular veins in the neck; superficial and deep veins and arteries in the arms, legs and abdomen; and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

The system has Vascular Measurements and Calculation Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

#### **Superficial Imaging Applications**

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of conventional or superficial musculoskeletal structures and surrounding anatomical structures to evaluate the presence or absence of pathology. The system may be used to acquire patient electrocardiogram for synchronizing the diastolic and systolic capture of ultrasound images.

**Intraoperative Imaging Applications**

The system transmits ultrasound energy into various parts of the body of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), and Pulsed Wave Doppler (PWD) to obtain images and blood flow velocity that provide guidance during intraoperative procedures.

**Transcranial Imaging Applications**

The system transmits ultrasound energy into the cranium of adult patients creating 2D (B), Color Doppler (CD), Color Power Doppler (CPD), Pulsed Wave Doppler (PWD), and Continuous Wave Doppler (CWD) to obtain images and blood flow velocity of the brain and surrounding anatomical structures to evaluate the presence or absence of pathology.

The system provides Measurement Packages that provide information that may be used adjunctively with other medical data obtained by a physician for clinical diagnosis purposes.

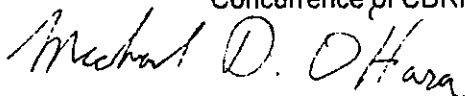
Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

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Division Sign-Off -Office of In Vitro Diagnostic Devices  
Division of Radiological Health (DRH)

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## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **SC2000 Diagnostic Ultrasound System**

Intended Use: **Ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: 3D	Other: Real Time 3D
Ophthalmic												
Fetal		P	P	P	P	P	P		P*	P		P
Abdominal		P	P	P	P	P	P		P*	P		
Intraoperative Abdominal		P	P	P	P	P	P		P*	P		
Intraoperative Neurological												
Pediatric		P	P	P	P	P	P		P*	P	P	P
Small Organ (specify)												
Neonatal Cephalic												
Adult Cephalic		P	P	P	P	P	P		P*	P		
Cardiac		P	P	P	P	P	P		P*	P	P	P
Trans-esophageal		P	P	P	P	P			P*		P	
Transrectal												
Transvaginal												
Transurethral												
Intra-Luminal		P	P	P	P	P	P		P*			P
Peripheral Vessel		P	P	P	P	P	P	P	P*	P		
Laparoscopic												
Musculo-skeletal Conventional		P	P	P		P	P	P	P*	P		
Musculo-skeletal Superficial		P	P	P		P	P	P	P*	P		
Other (Neonatal Cardiac)		P	P	P	P	P	P		P*	P		
Other (Intra-Cardiac)		P		P	P	P	P		P*			P

N=new indication. P= Previously Cleared in 510(k) K072365, K102017, K113179

### Additional Comments:

\*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)  
 Concurrence of CDRH, Office of In-Vitro Diagnostics (OIVD)  
 Prescription Use (Per 21 CFR 801.109)

Division Sign-Off -Office of In Vitro Diagnostic Devices

510(k) \_\_\_\_\_

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **9L4**

Indications for Use: **Ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal										
Peripheral Vessel		P	P	P		P	P	P	P*	P
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P	P	P	P*	P
Musculo-skeletal Superficial		P	P	P		P	P	P	P*	P
Other (specify)										

N=new indication. P = Previously Cleared in 510(k) K072365, K102017, K113179

### Additional Comments:

\*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Prescription Use (Per 21 CFR 801.109)

Division Sign-Off -Office of In Vitro Diagnostic Devices

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## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **6C1HD**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P*	P
Abdominal		P	P	P	P	P	P		P*	P
Intraoperative Abdominal		P	P	P	P	P	P		P*	P
Intraoperative										
Pediatric		P	P	P	P	P	P		P*	P
Small Organ (specify)		P	P	P	P	P	P		P*	P
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal										
Peripheral Vessel		P	P	P	P	P	P		P*	P
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Abdominal Vascular)		P	P	P	P	P	P		P*	P

N=new indication. P = Previously Cleared in 510(k) K072365, K102017

### Additional Comments:

\*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In-Vitro Diagnostics (OIVD)

Prescription Use (Per 21 CFR 801.109)

Division Sign-Off -Office of In Vitro Diagnostic Devices

510(k) \_\_\_\_\_

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## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **VSM**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P			P*		P
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P			P*		P
Trans-esophageal		P	P	P	P	P			P*		P
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N=new indication. P = Previously Cleared in 510(k) K072365, K102017, K113179

**Additional Comments:**

\*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)  
 Concurrence of CDRH, Office of In-Vitro Diagnostics (OIVD)  
 Prescription Use (Per 21 CFR 801.109)

Division Sign-Off -Office of In Vitro Diagnostic Devices

510(k) \_\_\_\_\_

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **4V1c**

Intended Use: **Ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P *	P
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P *	P
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic		P	P	P	P	P	P		P *	P
Cardiac		P	P	P	P	P	P		P *	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Neonatal Cardiac)		P	P	P	P	P	P		P *	P

N=new indication. Previously Cleared in 510(k) K072365, K102017, K113179

**Additional Comments:**

**\*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE**

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## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **8V3**

Intended Use: **Ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P *	P
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P		P *	P
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P *	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Neonatal Cardiac)		P	P	P	P	P	P		P *	P

N=new indication. Previously Cleared in 510(k) K102017, K113179

**Additional Comments:**

\*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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510(k) \_\_\_\_\_



## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **CW2**

Intended Use: **Ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal										
Intraoperative Neurological										
Pediatric					P					
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					P					
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal										
Peripheral Vessel					P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N=new indication. Previously Cleared in 510(k) K072365, K102017, K113179

**Additional Comments:**

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510(k) \_\_\_\_\_

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **4Z1c**

Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal		P	P	P	P	P			P*	P	P
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P			P*	P	P
Small Organ (specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P			P*	P	P
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N=new indication. P = Previously Cleared in 510(k) K072365, K102017, K113179

**Additional Comments:**

\*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **AcuNav 8F and 10F Ultrasound Catheter**

Intended Use: Catheter is intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		P*		
Small Organ (specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*		
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal		P	P	P	P	P	P		P*		
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (Intra-Cardiac)		P	P	P	P	P	P		P*		

N=new indication. P = Previously Cleared in 510(k) K071234, K093812, K113179

### Additional Comments:

\*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler

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## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **ACUSON AcuNav™ V 10F Ultrasound Catheter**

Intended Use: Catheter is intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart of adult and pediatric patients as follows:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P	P		P*		P
Small Organ (specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*		P
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal		P	P	P	P	P	P		P*		P
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (Intra-Cardiac)		P	P	P	P	P	P		P*		P

N=new indication. P = Previously Cleared in 510(k) K081808, K113179

**Additional Comments:**

\*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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510(k) \_\_\_\_\_

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **SoundStar 10F Ultrasound Catheter**

Intended Use: Catheter is intended for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart:

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: Real Time 3D
Ophthalmic											
Fetal											
Abdominal											
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric											
Small Organ (specify) **											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P	P		P*		
Trans-esophageal											
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal		P	P	P	P	P	P		P*		
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (Intra-Cardiac)		P	P	P	P	P	P		P*		

N=new indication. P = Previously Cleared in 510(k) K070242, K113179

**Additional Comments:**

\*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler

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510(k) \_\_\_\_\_

## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **V7M**

Intended Use: **Ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging	Other: 3D
Ophthalmic											
Fetal											
Abdominal		P	P	P	P	P	P		P*	P	P
Intraoperative Abdominal											
Intraoperative Neurological											
Pediatric		P	P	P	P	P			P*		P
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac		P	P	P	P	P			P*		P
Trans-esophageal		P	P	P	P	P			P*		P
Transrectal											
Transvaginal											
Transurethral											
Intra-Luminal											
Peripheral Vessel											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other (specify)											

N=new indication. P = Previously Cleared in 510(k) K111674

**Additional Comments:**

\*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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## Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: **10V4**

Intended Use: **Ultrasound imaging or fluid flow analysis of the human body as follows:**

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other: Harmonic Imaging
Ophthalmic										
Fetal		P	P	P	P	P	P		P *	P
Abdominal		P	P	P	P	P	P		P *	P
Intraoperative Abdominal		P	P	P	P	P	P		P *	P
Intraoperative Neurological		P	P	P	P	P	P		P *	P
Pediatric		P	P	P	P	P	P		P *	P
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P *	P
Trans-esophageal										
Transrectal										
Transvaginal										
Transurethral										
Intra-Luminal										
Peripheral Vessel										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Neonatal Cardiac)		P	P	P	P	P	P		P *	P

N=new indication. Previously Cleared in 510(k) K111674

### Additional Comments:

\*Combinations include: B+M, B+PWD, B+CWD, B+Color Doppler, B+M+ Color Doppler, B+PWD+Color Doppler, B+CWD+Color Doppler, B+Power Doppler, B+M+Power Doppler, B+PWD+Power Doppler, B+CWD+Power Doppler, B+Clarify VE

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